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10/035,924	12/21/2001	Alastair McIndoe Hodges	USFSEN.060C2	2203
45416	7590	01/18/2005	EXAMINER	
LIFESCAN/NUTTER MCCLENNEN & FISH LLP 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			NOGUROLA, ALEXANDER STEPHAN	
		ART UNIT	PAPER NUMBER	
		1753		

DATE MAILED: 01/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/035,924	HODGES ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 October 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,3-10 and 12-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 10,16-18 and 20 is/are allowed.
- 6) Claim(s) 1,3-9,12-15,19,21 and 22 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 21 December 2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 01/20/2004.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

*Response to Amendment*

1. Applicants amendment of October 27, 2004 ("Amendment") does not render the application allowable.

*Status of Rejections pending since the Office action of April 27, 2004*

2. All of the statutory double patenting rejections under 35 U.S.C. 101 are withdrawn.
3. The nonstatutory double patenting rejections based on US 6,413,410 B1 against claims 2, 11, and 16-18 are withdrawn.
4. The nonstatutory double patenting rejections based on US 6,413,410 B1 against claims 7-9 have been rewritten in light of the Amendment.

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5. The nonstatutory double patenting rejections based on US 6,284,125 B1 against claims 2, 10, 11, and 14-18 are withdrawn.

6. The nonstatutory double patenting rejections based on US 6,284,125 B1 against claims 5-9 have been rewritten in light of the Amendment.

7. The rejections of claims 12 and 13 under 35 U.S.C. 112, first paragraph, are withdrawn.

8. The rejections of claims 3 and 4 under 35 U.S.C. 112, first paragraph, are largely maintained, but have been rewritten as appropriate in light of the Amendment. These claims do not convey choosing from within the electrochemical cell different electrode pairs (of fixed spacing). See the top of page 8 of the Amendment. Indeed, the working electrode and counter electrode in claim 1 upon which one more of the “additional steps” are performed are the same working electrode and counter electrode upon which one or more of the “other” steps are performed.

9. The rejections of claims 2, 11, and 12 under 35 U.S.C. 112, second paragraph, are withdrawn, but the rejections of claims 3-5 and 14 have been rewritten in light of the Amendment. For claims 5 and 14 Applicants should note that confusion as to whether there is one or more concentrations for the analyte arises since the redox species appears to be the

analyte (preamble). In other words, the distinction between "analyte" and "redox species" is not clear.

### ***Double Patenting***

10. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Non-Statutory Double Patenting Rejections based on U.S. Patent No. 6,413,410 B1

12. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3 and 6 of U.S. Patent No. 6,413,410 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the combination of claims 3 and 6 of U.S. Patent No. 6,413,410 B1, which each depend from claim 1, provides all of the limitations of claim 2 of the instant application.

13. Claim 7 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claim 3 of U.S. Patent No. 6,413,410 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 3 provides for the counter electrode to be spaced from the working electrode by a distance between about 10 microns and about 500 microns. So, having the effective cell volume less than about 1.5 microliters is just a matter of scaling the electrochemical cell to the expected sample volume.

14. Claims 8 and 9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 6,413,410 B1 in view of Pritchard et al. (US 5,762,770). Claim 1, from which claims 8 and 9 depend, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from

each other because providing a reagent, such as glucose oxidase, in an electrochemical measurement cell was known in the art at the time of the invention as shown by the “Table 1” that begins at the bottoms of columns 7 and 8 and continues into columns 9 and 10 in Pritchard et al.). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a reagent such as glucose oxidase as taught by Pritchard et al. in the invention of claim 3 of U.S. Patent No. 6,413,410 B1 because as using a reagent will increase the selectivity and sensitivity of the electrochemical cell towards the analyte of interest. As for glucose dehydrogenase in particular as seen in “Table 1” glucose dehydrogenase is appropriate if the analyte is glucose.

15. Claim 19 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3 and 6 of U.S. Patent No. 6,413,410 B1 in view of Kawaguri et al. (US 5,171,689) (“Kawaguri”). Claim 1, from which claim 19 depends, has been addressed above. Claims 3 and 6 of U.S. Patent No. 6,413,410 B1 does not require a porous membrane. Kawaguri teaches placing a porous membrane in an electrochemical cell for measuring a redox species, the electrochemical cell containing a working electrode and a counter electrode. See the abstract and Figure 1. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a porous membrane as taught by Kawaguri in the invention of claim 3 because as taught by Kawaguri interferants can be prevented from reaching and being absorbed to the measurement electrode. This results in a more accurate measurement. See col. 5:9-15 and

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col. 6:15-20.

16. Claim 21 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 6,413,410 B1 in view of Kawaguri et al. (US 5,171,689) ("Kawaguri"). Claim 3 meets all of the limitations of claim 21 except for the requirement of a porous membrane. Kawaguri teaches placing a porous membrane in an electrochemical cell for measuring a redox species, the electrochemical cell containing a working electrode and a counter electrode. See the abstract and Figure 1. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a porous membrane as taught by Kawaguri in the invention of claim 3 because as taught by Kawaguri interferants can be prevented from reaching and being absorbed to the measurement electrode. This results in a more accurate measurement. See col. 5:9-15 and col. 6:15-20.

17. Claim 22 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 6,413,410 B1 in view of Kawaguri et al. (US 5,171,689) ("Kawaguri"). Claim 2 meets all of the limitations of claim 22 except for the requirement of a porous membrane. Kawaguri teaches placing a porous membrane in an electrochemical cell for measuring a redox species, the electrochemical cell

containing a working electrode and a counter electrode. See the abstract and Figure 1. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a porous membrane as taught by Kawaguri in the invention of claim 2 because as taught by Kawaguri interferants can be prevented from reaching and being absorbed to the measurement electrode. This results in a more accurate measurement. See col. 5:9-15 and col. 6:15-20.

Non-Statutory Double Patenting Rejections based on U.S. Patent No. 6,284,125 B1

18. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 6,284,125 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because

(1) the step of “depleting the reduced or oxidized form of the redox species in the sample by oxidizing or reducing it at the working electrode” in claim 1 is inherent in the method of claim 3. Step (3) of claim 3 requires selecting the potential of the working electrode to electro-oxidize the redox species. This will deplete the reduced or oxidized form of the redox species by oxidizing or reducing it at the working electrode; and

(2) Claim 1 of U.S. Patent No. 6,284,125 B1, from which claim 3 depends, has all of the limitations further required by “additional steps” of claim 1 of the instant application.

19. Claim 5 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 4 of U.S. Patent No. 6,284,125 B1. Claim 1, from which claim 5 depends has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 4 requires the redox mediator to be a mediator and the concentration of the reduced or oxidized form of the mediator to be indicative of a concentration of the analyte.

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20. Claim 6 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 4 and 11 of U.S. Patent No. 6,284,125 B1. Claim 5, from which claim 6 depends has been addressed in the preceding paragraph. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 11 implies that the analyte is glucose since glucose concentration is determined.

21. Claim 7 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 6,284,125 B1. Claim 1, from which claim 5 depends has been addressed above. Although the conflicting claims are not

identical, they are not patentably distinct from each other because claim 3 provides for the electrodes to be separated by less than 500 microns. So, having the effective cell volume less than about 1.5 microliters is just a matter of scaling the electrochemical cell to the expected sample volume.

22. Claims 8 and 9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 3, 7, and 11 of U.S. Patent No. 6,284,125 B1 in view of Pritchard et al. (US 5,762,770). Claim 1, from which claim 8 depends has been addressed above. Although the combination of claims 3, 7, and 11 provide for using a redox mediator and determining the concentration of glucose no mention is made of proving a reagent, in particulate glucose dehydrogenase. Providing a reagent, such as glucose oxidase, in an electrochemical measurement cell was known in the art at the time of the invention as shown by the “Table 1” that begins at the bottoms of columns 7 and 8 and continues into columns 9 and 10 in Pritchard et al.). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a reagent such as glucose oxidase as taught by Pritchard et al. in the invention of the combination of claims 3, 7, and 11 of U.S. Patent No. 6,284,125 B1 because as using a reagent will increase the selectivity and sensitivity of the electrochemical cell towards the analyte of interest. As for glucose dehydrogenase in particular as seen in “Table 1” glucose dehydrogenase is appropriate if the analyte is glucose.

23. Claim 19 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 6,284,125 B1. Claim 1, from

which claim 19 depends, has been addressed above. Claim 3 does not require a porous membrane. Kawaguri teaches placing a porous membrane in an electrochemical cell for measuring a redox species, the electrochemical cell containing a working electrode and a counter electrode. See the abstract and Figure 1. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a porous membrane as taught by Kawaguri in the invention of claim 3 because as taught by Kawaguri interferants can be prevented from reaching and being absorbed to the measurement electrode. This results in a more accurate measurement. See col. 5:9-15 and col. 6:15-20.

24. Claim 21 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 6,284,125 B1 in view of Kawaguri et al. (US 5,171,689) ("Kawaguri"). Although the conflicting claims are not identical, they are not patentably distinct from each other because

(a) the step of "depleting the reduced or oxidized form of the redox species in the sample by oxidizing or reducing it at the working electrode" in claim 21 is inherent in the method of claim 3. Step (3) of claim 3 requires selecting the potential of the working electrode to electro-oxidize the redox species. This will deplete the reduced or oxidized form of the redox species by oxidizing or reducing it at the working electrode; and

(b) Kawaguri teaches placing a porous membrane in an electrochemical cell for measuring a redox species, the electrochemical cell containing a working electrode and a counter electrode. See the abstract and Figure 1. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a porous membrane as taught by

Kawaguri in the invention of claim 3 because as taught by Kawaguri interferants can be prevented from reaching and being absorbed to the measurement electrode. This results in a more accurate measurement. See col. 5:9-15 and col. 6:15-20.

25. Claim 22 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,284,125 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because

(a) the step of “depleting the reduced or oxidized form of the redox species in the sample by oxidizing or reducing it at the working electrode” in claim 22 of the instant application is inherent in the method of claim 1 of U.S. Patent No. 6,284,125 B1. Step (3) of claim 1 of U.S. Patent No. 6,284,125 B1 requires selecting the potential of the working electrode to electro-oxidize the redox species. This will deplete the reduced or oxidized form of the redox species by oxidizing or reducing it at the working electrode;

(b) barring evidence to the contrary, such as unexpected results, having the counter electrode spaced from the working electrode by a distance greater than about 500 microns is just a matter of scaling the electrochemical cell for the expected amount of sample. Also, claim 3 of U.S. Patent No. 6,284,125 B1 implies that claim 1 contemplates having the counter electrode spaced from the working electrode by a distance greater than about 500 microns, since claim 3 limits the distance to less than 500 microns; and

(c) Kawaguri teaches placing a porous membrane in an electrochemical cell for measuring a redox species, the electrochemical cell containing a working electrode and a counter electrode. See the abstract and Figure 1. It would have been obvious to one with ordinary skill

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in the art at the time the invention was made to provide a porous membrane as taught by Kawaguri in the invention of claim 1 because as taught by Kawaguri interferants can be prevented from reaching and being absorbed to the measurement electrode. This results in a more accurate measurement. See col. 5:9-15 and col. 6:15-20.

***Claim Rejections - 35 USC § 112***

26. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for providing an electrochemical cell having a working electrode and a counter electrode, wherein the counter electrode is spaced from the working electrode by a distance of between about 10 microns and about 500 microns and so that reaction products from the counter electrode arrive at the working electrode, does not reasonably provide enablement for providing an electrochemical cell having a working electrode and a counter electrode, wherein the counter electrode is spaced from the working electrode by a distance of between about 10 microns and about 500 microns and *then later* during the measurement process selecting the distance between the working electrode and the counter electrode so that reaction products from the counter electrode arrive at the working electrode. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant's disclosure only discusses an electrochemical cell having fixed dimensions. While one with ordinary skill in the art, in light of the disclosure, could before manufacturing the electrochemical cell select the distance between the counter electrode and the working electrode so that the reaction products from the counter electrode arrive at the working electrode and also have the distance between the counter electrode and the working electrode be between about 10 microns and about 500 microns, one could not construct the electrochemical cell so that the distance between the distance between the counter electrode and the working electrode could be changed during the measurement process. To modify Applicant's disclosed cell allowing for varying the distance between the counter electrode and working electrode so would require undue experimentation.

27. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention. Claim 4 requires the "additional steps" of claim 1 to be conducted concurrently with the "other" steps of claim 1. However, the "other" steps of claim 1 and the "additional steps" of claim 1 are steps that must be performed in sequence and thus can not be performed concurrently; that is, there is an inherent temporal sequence to the "other" steps and "additional steps" of claim 1. For example, the measuring step must follow the depleting step, which must follow the applying step. Similarly, the obtaining step must follow the estimating step, which must follow the step of selecting a potential.

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28. Claim 12 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for providing an electrochemical cell having a working electrode and a counter electrode, wherein the counter electrode is spaced from the working electrode by a distance greater than about 500 microns and so that reaction products from the counter electrode arrive at the working electrode, does not reasonably provide enablement for providing an electrochemical cell having a working electrode and a counter electrode, wherein the counter electrode is spaced from the working electrode by a distance of greater than about 500 microns and *then later* during the measurement process selecting the distance between the working electrode and the counter electrode so that reaction products form the counter electrode arrive at the working electrode. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant's disclosure only discusses an electrochemical cell having fixed dimensions. While one with ordinary skill in the art, in light of the disclosure, could before manufacturing the electrochemical cell select the distance between the counter electrode and the working electrode so that the reaction products from the counter electrode arrive at the working electrode and also have the distance between the counter electrode and the working electrode greater than about 500 microns, one could not construct the electrochemical cell so that the distance between the counter electrode and the working electrode could be changed during the measurement process. To modify Applicant's disclosed cell allowing for varying the distance between the counter electrode and working electrode so would require undue experimentation.

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29. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention. Claim 13 requires the “additional steps” of claim 10 to be conducted concurrently with the “other” steps of claim 10. However, the “other” steps of claim 10 and the “additional steps” of claim 10 are steps that must be performed in sequence and thus cannot be performed concurrently; that is, there is an inherent temporal sequence to “other” steps and the “additional steps”. For example, the measuring step must follow the depleting step, which must follow the applying step. Similarly, the obtaining step must follow the estimating step, which must follow the step of selecting a potential.

30. Claims 1, 3-5, 14, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

- a) Claim 1 requires the distance between the counter electrode and the working electrode to be between about 10 microns and about 500 microns. Claim 1 also requires “selecting a distance between the working electrode and the counter electrode so that reaction products from the counter electrode arrive at the working electrode.” It is not clear
  - (i) whether the distance between the counter electrode and the working electrode can be changed, that is, whether the electrochemical cell has adjustable dimensions, and (ii) whether “selecting a distance step” allows for the distance between the counter electrode

and the working electrode to be outside the range of between about 10 microns and about 500 microns. Claim 3 adds further indefiniteness since claim 3 requires the step of selecting the distance between the counter electrode and the working electrode to be performed after the step of providing the electrochemical cell of claim 1. Applicants' arguments further add indefiniteness because these claims do not convey choosing from within the electrochemical cell different electrode pairs (of fixed spacing).

b) Claim 3 requires the "additional steps" of claim 1 to be conducted after the "other" steps of claim 1. It is not clear whether this will result in two separate measurements, not necessarily the same, indicative of the concentration of the reduced or oxidized form of the redox species; and

c) Claims 5 and 14: how many concentrations can the analyte have ("a concentration of an analyte")? Applicants should note that confusion as to whether there is one or more concentrations for the analyte arises since the redox species appears to be the analyte (preamble). In other words, the distinction between "analyte" and "redox species" is not clear.

31. Note that dependent claims will have the deficiencies of base and intervening claims.

***Claim Rejections - 35 USC § 103***

32. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

33. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

34. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

35. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diebold et al. (5,437,999) ("Diebold") over Szuminsky et al. (US 5,108,564) ("Szuminsky").

Addressing claim 21, Diebold teaches a method for determining the concentration of a reduced or oxidized form of a redox species in an electrochemical cell (abstract), the method comprising the steps of

providing an electrochemical call having a working electrode (11) and a counter electrode (48);

allowing ingress of a sample into the electrochemical cell, the sample substantially covering the working electrode and the counter electrode (col. 12, ll. 43-55, which teaches sample filling the capillary space);

applying an electric potential difference between the electrodes sufficient to oxidize or reduce the redox species at the working electrode, thereby producing a reduced or oxidized form of the redox species (col. 12, ln. 63 – col. 13, ln. 2);

depleting the reduced or oxidized form of the redox species in the sample by oxidizing or reducing it at the working electrode (implied by col. 12, ll. 18-24, which teaches that the redox species produces an electrochemically-measurable signal); and thereafter

measuring a charge passed at the working electrode, the charge indicative of the amount of reduced or oxidized form of the redox species depleted in the sample (col. 13, ll. 6-8).

Diebold does not mention the distance between the working electrode and the counter electrode, in particular whether this distance is between about 10 microns and about 500 microns. However, Diebold does teach using a MYLAR™ substrate of approximately

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10 mil thickness, which is 254 microns, and a MYLAR™ spacer (col. 7, ll. 55-57). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use the same 10 mil thick MYLAR™ material for the spacer, and thus have the working electrode and counter electrode 254 microns apart, because the electrochemical cell is designed for making highly-accurate electrochemical measurements on very small sample sizes (col. 2, ll. 1-12 and col. 12, ll. 35-42).

Diebold also does not mention providing a porous membrane in the electrochemical cell. Szuminsky discloses providing a porous membrane (wicking material) in an electrochemical measurement cell. See col. 7, ll. 68. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a membrane as taught by Szuminsky in the invention of Diebold because as taught by Szuminsky this will facilitate spread of the sample over the reagent. It should be noted that Szuminsky discloses blood as a sample as does Diebold.

Addressing claim 22, Diebold et al. teaches a method for determining the concentration of a reduced or oxidized form of a redox species in an electrochemical cell (abstract), the method comprising the steps of

providing an electrochemical cell having a working electrode (11) and a counter electrode (48);

allowing ingress of a sample into the electrochemical cell, the sample substantially covering the working electrode and the counter electrode (col. 12, ll. 43-55, which teaches sample filling the capillary space);

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applying an electric potential difference between the electrodes sufficient to oxidize or reduce the redox species at the working electrode, thereby producing a reduced or oxidized form of the redox species (col. 12, ln. 63 – col. 13, ln. 2);

depleting the reduced or oxidized form of the redox species in the sample by oxidizing or reducing it at the working electrode (implied by col. 12, ll. 18-24, which teaches that the redox species produces an electrochemically-measurable signal); and thereafter

measuring a charge passed at the working electrode, the charge indicative of the amount of reduced or oxidized form of the redox species depleted in the sample (col. 13, ll. 6-8).

Diebold et al. does not mention the distance between the working electrode and the counter electrode, in particular whether this distance is greater than about 500 microns.

However, Diebold et al. does teach configuring the electrochemical cell to be able to make a measurement on a sample volume between about 3-20 microliters (col. 12, ll. 35-42) and having the working and counter electrodes closely spaced (Figures 5 and 6, which shows the counter electrode and working electrode closely spaced, and col. 8, ll. 37-50, which teaches that the counter electrode and the working electrode are so closely spaced as to easily draw in sample by capillary action). Barring evidence to the contrary, such as unexpected results, having the counter electrode spaced from the working electrode by a distance greater than about 500 microns is just a matter of scaling the electrochemical cell for the expected amount of sample.

Diebold also does not mention providing a porous membrane in the electrochemical cell. Szuminsky discloses providing a porous membrane (wicking material) in an electrochemical measurement cell. See col. 7, ll. 68. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a membrane as taught by Szuminsky in the

invention of Diebold because as taught by Szuminsky this will facilitate spread of the sample over the reagent. It should be noted that Szuminsky discloses blood as a sample as does Diebold.

*Allowable Subject Matter*

36. Claims 10, 16-18, and 20 are allowed.
37. Claims 14 and 15 would be allowable if rewritten to overcome the rejection under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
38. The following is a statement of reasons for the indication of allowable subject matter:
  - a) Claim 10 includes the “additional steps” of previous claim 11 and requires the first counter electrode to be spaced from the working electrode by a distance greater than about 500 microns and the second counter electrode to be spaced from the working electrode by less than about 500 microns;
  - b) Claims 14-18 and 20 depend directly or indirectly from allowable claim 10; and

c) Bohs et al. (US 5,399,256) ("Bohs") was cited as an "X" reference against claims 1-3, 5-10, 14, and 15 in the European Search Report for PCT EP 03007604. McClintock (US 4,554,064 A) ("McClintock") was cited as an "X" reference against claims 1, 3, 5-7, 10, and 15 in the European Search Report for PCT EP 03007604. Nippon Telegraph and Telephone (JP 05002007 A) ("NIPPON TT") was cited as an "X" reference against claims 1, 4, 5, 8, 10, 11, 15, 16 in the European Search Report for PCT EP 03007604. Independent claims 1 and 10 each require "additional steps" not disclosed or suggested by these references, such as the "determining", "estimating", and "obtaining steps". New claims 21 and 22 each require a porous membrane.

*Final Rejection*

39. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Alex Noguerola  
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AU 1753  
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